

REMARKS

Claims 1 – 9, 12 – 18, and 20 are currently pending. Claims 1 and 20 are the pending independent claims. In the Office Action, the Examiner rejected Claim 19 under Section 101 as allegedly being directed to non-statutory subject matter. The Examiner also rejected Claim 17 under Section 112, first paragraph, as allegedly failing to satisfy the enablement requirement. In addition, the Examiner rejected Claims 3 and 9 under Section 112, second paragraph, as allegedly being indefinite. On the merits, Claims 1, 6, 7, and 10 were rejected as allegedly being anticipated by U.S. Patent No. 6,515,116 to Suh et al. (“Suh”). In addition, Claims 1 – 5, 8, and 18 were rejected as allegedly being obvious over European patent application EP 0,415,522 to Collin. The subject matter of Claims 11 – 16 was indicated as being allowable over the prior art, but the claims were formally objected to as being dependent upon a rejected base claim.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

I. **The Section 101 Rejection.**

First, the Examiner has rejected Claim 19 under Section 101 as allegedly being directed to non-statutory subject matter. In particular, the Examiner contends that the claimed recitation of a use, without setting forth the steps involved in the process, results in an improper definition of a process.

In response, Claim 19 has been cancelled, and new independent Claim 20 has been added to the case.

II. **The Enablement Rejection.**

Second, the Examiner contends that Claim 17 lacks enablement under Section 112, first paragraph. Specifically, the Examiner contends that the claim refers to “analogues” of clarithromycin but does not give any guidance to what these analogues are or how to make them. The Examiner also objects to the disclosure of the specification on the same basis.

In response, Claim 17 is amended herein to delete the reference to “analogues” of clarithromycin. In view of this amendment, it is submitted that the enablement rejection has been overcome and that the same should now be withdrawn.

III. The Indefiniteness Rejections.

Under Section 112, second paragraph, the Examiner contends that Claim 3 is indefinite due to the recitation of “others” in the list of pharmaceutically acceptable excipients. In response, Claim 3 had been amended to delete the reference to “others” and to specify that the poor solvent referred to is an aqueous solution comprising water and at least one pharmaceutically acceptable excipient selected from the group consisting of binders, buffers, emulgators, and surfactants.

In addition, the Examiner contends that Claim 9 is indefinite due a lack of antecedent basis for the limitation “the particles.” In response, Claim 9 has been amended to specify that the active substance comprises particles thereof which are large, brittle and/or porous.

In view of this amendment, it is submitted that the indefiniteness rejections have been overcome and that the same should now be withdrawn.

IV. The Prior Art Rejections.

Finally, turning to the prior art, the Examiner contends that Claims 1, 6, 7, and 10 are anticipated by the Suh patent. The Examiner further contends Claims 1 – 5, 8, and 18 are obvious over the Collin reference. On the other hand, the Examiner acknowledge that the subject matter of Claims 11 – 16 is allowable over the prior art.

In response to these rejections, the Applicants have amended Claim 1 to incorporate the limitations of Claim 11 and specify that the active substance comprises micronized clarithromycin. In view of this amendment to Claim 1, Claims 10 and 11 are herein cancelled. Accordingly, Claim 1, and each of its dependent claims, patentably distinguish over the prior art, and the prior art rejections should now be withdrawn.

Application No. 10/521,295
March 6, 2009

It is further noted that these amendments are made in the interest of expeditious prosecution of the current application and while reserving the right to prosecute claims of a broader scope in one or more continuation applications.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12-2355**.

Respectfully submitted,
LUEDEKA, NEELY & GRAHAM, P.C.
By: /J. David Gonce/
J. David Gonce
Registration No. 47,601

Date: March 6, 2009
P.O. Box 1871
Knoxville, Tennessee 37901
(865) 546-4305